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Balloon-expandable Tantalum Wiktor Stents: Initial Results of Implantation in Autologous Saphenous Vein Grafts in Pigs
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The behavior of balloon-expandable stents (BES) in vein grafts of experimental animals or man has undergone only limited study. We evaluated the efficacy of the tantalum Wiktor BES (Medtronic, Inc.) in a model of autologous saphenous vein grafting in 21 pigs, in which a segment of overdilated saphenous vein was interposed in each carotid artery. Five to six weeks after grafting angiography was performed. Complete occlusion was observed in 13/42 grafts (31%). Four intervention groups were studied in the patent grafts (n=29): 1. a single BES (4.0 mm) was placed (n=11 grafts, 11 BES), 2. multiple BES (n=6 grafts, 15 BES), 3. the graft was left untreated (n=7 grafts), 4. angioplasty with a 4 mm balloon was performed (n=5 grafts). During the procedure heparin was administered but no anticoagulation was given during follow-up. Four weeks later angiography was repeated, and then the vein grafts were harvested for analysis by light, transmission and scanning electron microscopy. Angiographic results prior to sacrifice:

	Grafts	Patency
untreated	(n=7)	83%
single BES	(n=11)	88%
multiple BES	(n=6)	25%*
balloon	(n=5)	80%

* P<0.05 vs single BES

It is concluded that in this aggressive model of autologous saphenous vein grafting, resulting in early hyperplasia, BES can be placed safely. Although initial results with single stents are promising, the implantation of multiple stents is associated with a significantly higher risk of graft occlusion.

2:45

ULTRASOUND GUIDED HOLMIUM:YAG LASER ANGIOPLASTY

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Current angioplasty devices are limited by arterial wall dissection and perforation, and by early recurrence from inadequate debulking of lesions. This study evaluated intravascular ultrasound as guidance for concentric laser recanalization of arterial occlusions. Twelve, 2-4 cm length canine iliac artery occlusions were recanalized at 2 wks (organizing thrombus) to 12 wks (firm fibrous lesions) using a Holmium:YAG laser (2100 nm wavelength, Trimedyne, Inc.) in free-running, FRM, (250 usec pulse, 5 Hz), n=9; and Q-switched, QSM modes (200 ns pulse, 6 Hz), n=3. A 200 um (n=6) or 600 um (n=6) fiberoptic was centered in the artery coaxial to a 5Fr rotating A scan intravascular ultrasound probe (C-VIS, Inc). The fiber was slowly advanced through the obstruction, and in 8 occlusions was used as a guide for passage of either a 1.6 mm (n=4) or 3.0 mm (n=4) diameter multifiber catheter (19 x 100 or 200 um fibers) to further debulk the lesion. In all cases, ultrasound guidance enabled concentric initial recanalization of occlusions. Both QSM and FRM modes produced tissue ablation, with FRM producing more tissue fragmentation and thermal effect. Ultrasound images accurately diagnosed the location of lesions compared to angioscopic views and pathologic analysis of the specimens. This study suggests that ultrasound guided laser energy enables initial concentric recanalization of arterial occlusions. Current devices are limited by inadequate tissue removal once initial recanalization is accomplished inhibiting ultrasound visualization, complete removal of lesions, and prevention of vessel wall perforation or dissection.

3:00

HOLMIUM LASER ANGIOPLASTY IN CORONARY ARTERIES

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Holmium laser is a 'cold', pulsed, solid state laser that is easier to use than excimer laser. To evaluate its clinical utility, 29 patients (avg. 58 years) with symptomatic coronary disease were studied. Thirty lesions in the following arteries were treated: 15 (50%) left anterior descending, 5 (17%) right coronary, 4 (13%) circumflex and 6 (20%) saphenous bypass grafts.

Six (25%) of the 24 lesions in native arteries were due to angioplasty restenosis. Average lesion length was 1.5 cm. A 1.5mm or 2.0mm tapered-tip, multifiber laser catheter was advanced over-the-wire while emitting 450-600 millijoules per pulse at 5 Hertz. Mean % stenosis decreased from 86% to 46% after lasing with a mean of 158 pulses (33 seconds). Initial laser success was 81% and overall procedural success was 97%. All but 9 lesions had adjunctive balloon angioplasty. Complications included one dissection with branch occlusion, one retroperitoneal hematoma and one acute closure.

Conclusions:

- 1) Holmium laser angioplasty is capable of reducing coronary artery stenosis in both native vessels and bypass grafts.
- 2) Follow-up studies are in progress to assess long term efficacy of procedure.

3:15

A NEW PERCUTANEOUS INTRA-ARTERIAL CARDIAC SUPPORT SYSTEM: FIRST CLINICAL USE

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A new percutaneous Intra-arterial Cardiac Support System (ICS), consisting of an occlusively inflating balloon catheter positioned in the ascending aorta, has been designed to unload the myocardium and augment coronary perfusion more effectively than the conventional IABP. Five patients in cardiogenic shock despite IABP support (1 acute MI, 3 postoperative, 1 decompensated cardiomyopathy) were supported with ICS for a mean of 100 hours. Two patients were successfully weaned from ICS. No ICS-related adverse effects were encountered. The patient presenting with an acute MI was stabilized on the ICS for 24 hours, underwent CABG, remained on ICS 4 days postoperatively, and survived to be discharged. Five months following discharge, he remained in NYHA Class II. Conclusion: The ICS may effectively support patients in cardiogenic shock refractory to conventional therapy.